

Decision Memo for Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) tests (Removal of Unspecified Joint Replacements) (CAG-00246N)

Decision Summary

CMS has determined that ICD-9-CM code V43.60, Unspecified joint replaced by other means, does not flow from the existing narrative for conditions for which prothrombin time (PT) tests are reasonable and necessary. We intend to modify the list of "ICD-9-CM Codes Covered by Medicare" in the NCD for PT to exclude this code.

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Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO: Administrative File: CAG-00246N Prothrombin Time (Removal of ICD-9-CM Codes for Unspecified Joint Replacements)

FROM:

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RE: Coding Analyses for Prothrombin Time Tests

DATE: July 27, 2004

I. Decision

CMS has determined that ICD-9-CM code V43.60, Unspecified joint replaced by other means, does not flow from the existing narrative for conditions for which prothrombin time (PT) tests are reasonable and necessary. We intend to modify the list of "ICD-9-CM Codes Covered by Medicare" in the NCD for PT to exclude this code.

II. Background

On June 24, 2004 CMS began a coding analysis for evaluation of ICD-9-CM covered codes list for the PT NCDs. Basic plasma coagulation function is readily assessed with a few simple laboratory tests: the PTT, PT, thrombin time or a quantitative fibrinogen determination. The PT assesses the extrinsic or tissue factor dependent pathway. The test also evaluates the common coagulation pathway involving all the reactions that occur after the activation of factor X.

III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. These NCDs included the PT test. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM Codes Covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM Codes Denied," and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM Codes that do not Support Medical Necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the PT NCD that any ICD-9-CM code not listed in either of the ICD-9-CM covered or not covered sections would be categorized into this group that does not support medical necessity.

IV. Timeline of Recent Activities

On June 24, 2004, CMS open an internally generated coding analysis item regarding the PT and partial thromboplastin time (PTT) NCDs after receiving several pieces of correspondence expressing confusion regarding the inclusion of ICD-9-CM code V43.60, Unspecified joint replaced by other means, in the list of "ICD-9-CM Codes Covered by Medicare." We posted, a tracking sheet to the Internet site (<http://cms.hhs.gov/mcd/viewtrackingsheet.asp?id=131>), soliciting public comment for 30 days on the appropriateness of removing code V43.60 from the list of covered diagnoses for PT and PTT testing. At the end of the public comment period, July 24, 2004, we had not received any comments. After posting the tracking sheet, we noted that code V43.60 is not currently included in the list of covered codes for PTT testing. Thus, this analysis is related exclusively to PT testing.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

VI. CMS Analysis

As noted above, we have taken the position that the "ICD-9-CM Codes Covered by Medicare" list is intended to contain only those codes that flow from the narrative indications in the NCD. The narrative indication for PT testing reads as follows:

1. A PT may be used to assess patients taking warfarin. The prothrombin time is generally not useful in monitoring patients receiving heparin who are not taking warfarin.
- 2.

A PT may be used to assess patients with signs or symptoms of abnormal bleeding or thrombosis. For example: swollen extremity with or without prior trauma; unexplained bruising; abnormal bleeding, hemorrhage or hematoma; petechiae or other signs of thrombocytopenia that could be due to Disseminated Intravascular Coagulation.

3. A PT may be useful in evaluating patients who have a history of a condition known to be associated with the risk of bleeding or thrombosis that is related to the extrinsic coagulation pathway. Such abnormalities may be genetic or acquired. For example: dysfibrinogenemia; afibrinogenemia (complete); acute or chronic liver dysfunction or failure, including Wilson's disease and Hemochromatosis; disseminated intravascular coagulation (DIC); congenital and acquired deficiencies of factors II, V, VII, X; vitamin K deficiency; lupus erythematosus; hypercoagulable state; paraproteinemia; lymphoma; amyloidosis; acute and chronic leukemias; plasma cell dyscrasia; HIV infection; malignant neoplasms; hemorrhagic fever; salicylate poisoning; obstructive jaundice; intestinal fistula; malabsorption syndrome; colitis; chronic diarrhea; presence of peripheral venous or arterial thrombosis or pulmonary emboli or myocardial infarction; patients with bleeding or clotting tendencies; organ transplantation; presence of circulating coagulation inhibitors.
4. A PT may be used to assess the risk of hemorrhage or thrombosis in patients who are going to have a medical intervention known to be associated with increased risk of bleeding or thrombosis. For example: evaluation prior to invasive procedures or operations of patients with personal history of bleeding or a condition associated with coagulopathy prior to the use of thrombolytic medication.

After careful review of the narrative indications for PT testing, we have not found any indication that is appropriately linked with ICD-9-CM code V43.60. This ICD-9-CM code is a status code used to indicate that a patient has previously had a joint replaced. It is primarily useful to indicate this health history for patients about to undergo radiological or dental procedures so that the practitioner may be made aware of important medical history.

It is common clinical practice to place joint replacement patients on a post-operative regimen of anticoagulation therapy immediately following the procedure. If that therapy includes warfarin, it is medically necessary to also monitor that therapy with PT testing. However, the appropriate code for such monitoring is V58.61, Long-term (current) use of anticoagulants. Once administration of the therapy is discontinued, there is no indication for continued PT monitoring of a patient merely because they had a joint replacement.

Thus, we believe that the ICD-9-CM code V43.60, Unspecified joint replaced by other means, does not flow from the existing narrative indications in the PT testing NCD. We believe this code was placed on the covered list in error. Consequently, we intend to issue a recurring update to the edit module implementing the NCDs to remove ICD-9-CM code V43.60 from the list of the ICD-9-CM codes covered for PT tests.

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